REMARKS

Claims 1-19 are pending in this application. Claims 1, 3-9 and 12-19 have been amended as shown in Appendix A, attached hereto. No new matter has been added.

A. The Rejection Under 35 U.S.C. § 112 Should Be Withdrawn

On page 3 of the Office Action, claims 1-19 are rejected under the first paragraph of 35 U.S.C. § 112 as allegedly lacking enablement. Although Applicants respectfully disagree, the word "prodrug" has been deleted from the claims to expedite the allowance of the application.

In light of these amendments, the rejection under 35 U.S.C. § 112, first paragraph, is obviated. Therefore, Applicants respectfully submit that the claims 1-19, as amended, are in condition for allowance.

B. The Provisional Double Patenting Rejection

On pages 2-3 of the Office Action, claims 1-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-5, 7-18, 20-24 and 36-39 of co-pending U.S. Patent Application No. 09/853,617. In view of the terminal disclaimer filed concurrently herewith, Applicants respectfully request that this rejection be withdrawn.

Conclusion

For the foregoing reasons, Applicants respectfully submit that this application is in condition for allowance, early notice of which would be appreciated.

No fee is believed to be due for this response. However, if any fees be required to enter this response into the file of the application and/or to avoid abandonment of the application, please charge such fees to Pennie & Edmonds LLP's Deposit Account No. 16-1150.

Respectfully submitted,

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45,479

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Attachments

APPENDIX A: Marked Up Version of the Pending Claims

1. (Amended) A method of treating colon cancer or rectal cancer which comprises administering to a patient in need of such treatment a therapeutically effective amount of irinotecan, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, and a therapeutically effective amount of thalidomide, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof.

3. (Amended) The method of claim 1 wherein the irinotecan, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 25 to about 750 mg/m^2, and the thalidomide, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 1000 mg.

4. (Amended) The method of claim 3 wherein the irinotecan, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 500 mg/m^2, and the thalidomide, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 750 mg.

5. (Amended) The method of claim 4 wherein the irinotecan, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 350 mg/m^2, and the thalidomide, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 200 to about 500 mg.

6. (Amended) A method of increasing the dosage of irinotecan that can be safely and effectively administered to a patient, which comprises administering to a patient in need of such an increased dosage an amount of thalidomide, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, that is sufficient to reduce a dose-limiting adverse effect associated with the irinotecan.

7. (Amended) The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered prior to the administration of the irinotecan.

8. (Amended) The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered simultaneously with the administration of the irinotecan.

9. (Amended) The method of claim 6 wherein the thalidomide, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered after the administration of the irinotecan.

12. (Amended) The method of claim 6 wherein the thalidomide, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 1 to about 2000 mg.

13. (Amended) The method of claim 12 wherein the thalidomide, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 50 to about 1000 mg.

14. (Amended) The method of claim 13 wherein the thalidomide, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 100 to about 750 mg.

15. (Amended) The method of claim 14 wherein the thalidomide, or pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered in an amount of from about 200 to about 500 mg.

16. (Amended) A method of increasing the therapeutic efficacy of irinotecan which comprises administering to a patient in need of such increased therapeutic efficacy an

amount of thalidomide, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, that is sufficient to increase the therapeutic efficacy of irinotecan.

17. (Amended) The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered prior to administration of the irinotecan to the patient.

18. (Amended) The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered during administration of the irinotecan to the patient.

19. (Amended) The method of claim 16 wherein the thalidomide, or a pharmaceutically acceptable [prodrug,] salt, solvate, hydrate, or clathrate thereof, is administered after administration of the irinotecan to the patient.